

## REMARKS

Claims 50 and 64 are currently amended. Claim 58 is canceled. Claims 59, 60, 69 and 70 are withdrawn-currently amended. Claims 71 and 72 are new.

It is respectfully submitted that the present amendment presents no new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

### I: Restriction Requirement

Applicants urge that the Examiner review the withdrawn claims. Paragraph 2 of the rejection states that claims 55, 56, 57-60 (all drawn to non-elected species and 68-70 are withdrawn . . . At Paragraph 5 of the rejection states that Claims 50-54, 57-60 (drawn to elected species) and 64-67 are currently pending and under examination. Applicants request clarification on the withdrawn claims. Applicants urge that Claims 57, 59 and 60 should not be withdrawn.

### II. The Rejection of Claims 50-54, 64, 65 and 67 under the Doctrine of Obviousness-Type Double Patenting

Claims 50-54, 64, 65 and 67 are rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 14-30 of U.S. Patent No. 6,762,040.

Claim 50 is currently amended. Reconsideration is urged.

### III. The Rejection of Claim 64 under 35 U.S.C. 112

Claim 64 is currently amended. Reconsideration is urged.

### IV. The Rejection of Claims 58-60 under 35 U.S.C. 112 (Written Description)

Claim 58 is canceled; accordingly, this portion of the rejection is moot.

Claims 59-60 are rejected under 35 U.S.C. 112 as failing to comply with the written description requirement. This rejection is respectfully traversed.

The written description requirement of the Patent Code is fulfilled when the patent specification describes the claimed invention in sufficient detail such that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *See Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). The written description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. *See In re Marzocchi*, 169 USPQ 367 (CCPA 1971).

Under this standard, the Examiner's has erred and by not acknowledging that the

specification at least provides adequate written description support for the species encoded by SEQ ID NO:16. Reconsideration is urged. Further, the specification discloses, and one skilled in the art would clearly recognize, that the scope of the present invention includes the conditionally essential gene characterized as the *metE* sequence of *Bacillus subtilis* shown in positions 997 to 2199 of SEQ ID NO: 16. Moreover the specification discloses a conditionally essential gene is at least 90% or 95% identical to the *metE* sequence of *Bacillus subtilis* shown in positions 997 to 2199 of SEQ ID NO: 16. Reviewing the entire specification, an artisan would reasonably conclude that Applicants were not only in possession of the specified conditionally essential genes including the gene as specified in SEQ ID NO: 16, but also that Applicants had possession of highly related conditionally essential genes, as specified by the claims. Indeed, based on the high level of skill in the art, the phrase "conditionally essential gene is at least 90% identical to the *metE* sequence of *Bacillus subtilis* shown in positions 997 to 2199 of SEQ ID NO: 16" itself conveys to the artisan that Applicants were in possession of the claimed invention.

Notwithstanding the above, the Examiner has not provided sufficient evidence or reasoning to rebut that the specification provides an adequate written description for highly related conditionally essential genes. In this regard, the Examiner contends that a number of additional representative species are required to be disclosed. However, given the high degree of relatedness in the claims an extremely high degree of predictability exists as to the structure and function of conditionally essential genes falling within the claims.

Therefore, Applicants respectfully submit that the specification contains a sufficient description of the structural and functional characteristics of the claimed conditionally essential genes to fulfill the requirements of 35 U.S.C. 112. Reconsideration and withdrawal of the rejection are therefore respectfully requested.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

**V. The Rejection of claims 50-54, 64, 65 and 67 under 35 U.S.C. 102(e)**

Claims 50-54, 64, 65 and 67 stand rejected as being anticipated by U.S. 6,762,040 to Rasmussen (hereinafter referred to simply as "Rasmussen").

Initially, Applicants note that Claim 50 is currently amended, thus Applicants have been fully responsive to the Examiner's rejections. Consideration of amended Claim 50 is urged.

Notwithstanding the above amendments, as currently amended, Claim 50 requires, *inter alia*, a bacterial host cell including at least two amplified copies of an amplification unit, wherein

the amplification unit is integrated in the genome of the bacterial host cell and the amplification unit comprises . . . an expressible conditionally essential gene . . . wherein the conditionally essential gene encodes an enzyme from the biosynthetic pathway of an amino acid, and wherein the conditionally essential gene if not functional would render the cell auxotrophic for the amino acid. Thus, the claimed cells will show, *inter alia*, growth because they are excellent in manufacturing the required amino acid. Nowhere does Rasmussen show such a requirement. Conversely, Rasmussen relates to cells which can metabolize an inhibitory compound produced endogenously in the cells from an externally added substance or precursor (e.g., galactose). Accordingly, Rasmussen is deficient and fails to show cells which make the requisite amino acid in accordance with claim 50. Reconsideration is urged.

**VI. New Claims 71 and 72**

New claim 71 is added. New claim 71 encompasses previously presented Claim 66.

New claim 72 is added. Consideration is urged.

No new matter is added. Should any additional fees be due, the USPTO is authorized to charge the deposit account of Novozymes North America, Inc., i.e., Deposit Account No. 50-1701.

**VII: Claim Objections**

Claims 58 is canceled. Claims 59 and 60 are currently amended. Reconsideration is urged.

Claim 66 was objected to for depending upon an independent claim that was not allowed. Reconsideration is urged. New claim 70 should be immediately allowable.

#### **VIII. Conclusion**

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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